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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/777,825

02/11/2004

Mark E. Cook

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EXAMINER

GUPTA, ANISH

ART UNIT

PAPER NUMBER

1654

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/777,825	Applicant(s) COOK ET AL.	
	Examiner Anish Gupta	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11-8-06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5-10-04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, in the reply filed on 11-8-06 is acknowledged. The traversal is on the ground(s) that there would not be serious burden since the subject matter is highly related. In view of Applicants the restriction is hereby withdrawn. However, the election of species imposed in the restriction requirement is still deemed proper and is maintained.

Applicants elected the species Trehalose and anti-PLA2. Claims 1-3, 5-23 read on the elected species. In course of searching, prior art was found that anticipated other species, this has been applied below. Claim 4 has been withdrawn as corresponding to non-elected species.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 5-7, 9-10, 14-17 and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Draber et al. (J. Of Immunogical methods).

The claims are drawn to a method for heat stabilizing a specific binding activity of a protein by subjecting the protein to a saccharide.

The reference teaches the stabilization of antibodies using trehalose. The reference specifically teaches a method where the ascetic fluids or purified mAbs were freeze dreid in the presence of trehalose (see page 38). This meets the limitation of claims 1-3 and 5-7. The trehalose freeze dried preparation of IgG and IgM were found to be more stable (see page 41).

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3. Claims 1-3, 5-7, 9-10, 13, 14-17 and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Draber et al. (J. Of Immunogical methods).

The claims are drawn to a method for heat stabilizing a specific binding activity of a protein by subjecting the protein to a saccharide.

The reference teaches a method of stabilizing spray dried protein using threhalose. The reference specifically states using anti-IgE amonoclonal antibody (see page 351), thereby meeting limitation of claim 7. The reference further states that formulations were prepared by dialysis of the antibody in water and then adding the carbohydrate (see page 351, Formulations). The carbohydrate included threhalose (See page 351). The formulation, thereafter, were filtered and then spray dried (see page 351), thereby meeting the limitation of claim 13.

The reference anticipates the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and

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invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-3, 5-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (US6213930) in view of Draber et al. or Wantanbe et al.

The claims are drawn to a method for heat stabilizing a specific binding activity of a protein by subjecting the protein to a saccharide.

The reference of Cook et al. the use of anti-phospholipids A2 antibodies to enhance growth or improve animal feed (see abstract). The reference states a producer animal is immunized with a peptide or protein, such as PLA.sub.2, against which antibodies are desired so that the producer animal produces an antibody to said peptide or protein. A substance containing the antibody is obtained from said producer animal. The antibody can be subject to further purification if desired or can be used without further preparation in an animal feed (see col. 3, lines 63-67). Further, An egg preparation, e.g., egg yolks or whole eggs, containing the anti-PLA.sub.2 antibody can be collected and homogenized to form an emulsion. Thereby meeting the imitation of claim 7-12. The resulting emulsion can be dried to form a powder containing the anti-PLA2 antibody. This powder can then be formulated in a manner appropriate to the administration route and then administered to the desired animals using methods known in the art. The preparation is preferably administered orally, most preferably as a supplement to the animal's diet. (see col. 4, lines 14-22). The difference between the prior art and the instant application is that the reference does not teach the use of trehalose.

However, Draber et al. teach the stabilization of antibodies using trehalose. The reference specifically teaches a method where the ascetic fluids or purified mAbs were freeze dreid in the


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presence of trehalose (see page 38). Trehalose provides effective stabilization during freeze-drying of IgM and such preparations can be stored at elevated temperatures (see page 41). The trehalose freeze dried preparation of IgG and IgM were found to be more stable (see page 41). Trehalose confers unique thermostability to biomolecules including liposome-hemoglobin, air-dried antibodies (see page 41).

The reference of Andya et al. teach that anti-IgE monoclonal antibody during spray drying resulted in a stabilized antibody product and a decrease rates of aggregation when trehalose was utilized (see page 355).

Therefore, it would have been obvious to one of ordinary skill in the art to use trehalose with anti-PLA.sub.2 antibody because trehalose confers thermostability to dried formulations.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (571) 272-0562. The fax phone number of this group is (571)-273-8300.


Anish Gupta
Patent Examiner